March 27, 2003

Sarah Loftus McLallen
Manager, CHEMSTAR
The American Chemistry Council Petroleum Additives Panel
Health, Environmental, and Regulatory Task Group (HERTG)
1300 Wilson Boulevard
Arlington, VA 22209

Dear Ms. McLallen:

The Office of Pollution Prevention and Toxics is transmitting EPA's comments on the robust summaries and test plan for Zinc Dialkyldithiophosphate Category posted on the ChemRTK HPV Challenge Program Web site on November 27, 2002. I commend The American Chemistry Council Petroleum Additives Panel Health, Environmental, and Regulatory Task Group (HERTG) for their commitment to the HPV Challenge Program.

EPA reviews test plans and robust summaries to determine whether the reported data and test plans will provide the data necessary to adequately characterize each SIDS endpoint. On its Challenge Web site, EPA has provided guidance for determining the adequacy of data and preparing test plans used to prioritize chemicals for further work.

EPA will post this letter and the enclosed comments on the HPV Challenge Web site within the next few days. As noted in the comments, we ask that The American Chemistry Council Petroleum Additives Panel Health, Environmental, and Regulatory Task Group (HERTG) advise the Agency, within 90 days of this posting on the Web site, of any modifications to its submission.

If you have any questions about this response, please contact Richard Hefter, Chief of the HPV Chemicals Branch, at 202-564-7649. Submit questions about the HPV Challenge Program through the "Contact Us" link on the HPV Challenge Program Web site pages or through the TSCA Assistance Information Service (TSCA Hotline) at (202) 554-1404. The TSCA Hotline can also be reached by e-mail at tsca-hotline@epa.gov.

I thank you for your submission and look forward to your continued participation in the HPV Challenge Program.

Sincerely,

*-S-*

Oscar Hernandez, Director
Risk Assessment Division

Enclosure

cc: C. Auer
A. Abramson
W. Penberthy
M. E. Weber

**EPA Comments on Chemical RTK HPV Challenge Submission:**
**Zinc Dialkyldithiophosphates**

## Summary of EPA Comments

The sponsor, The American Chemistry Council Petroleum Additives Panel Health, Environmental, and Regulatory Task Group, submitted a test plan and robust summaries to EPA for Zinc Dialkyldithio-phosphates dated September 24, 2002. EPA posted the submission on the ChemRTK HPV Challenge Web site on November 27, 2002. The category consists of 12 chemicals.

EPA believes that the category and test plan as proposed are not adequately supported. The submitter needs to provide a better basis for grouping the chemicals as proposed and also for extrapolating data for many of the SIDS endpoints, the health endpoints in particular. Many endpoints lacked robust summaries.

EPA's preliminary comments appear below. EPA requests that the submitter advise the Agency within 90 days of any modifications to its submission.

## EPA Comments on the Zinc Dialkyldithiophosphates Challenge Submission

### General

Robust summaries were provided for the mammalian toxicity data. These submitted robust summaries generally appear complete, although EPA did not evaluate data adequacy. Robust summaries were available for the biodegradation data but were not available for all other environmental fate data, or for any of the physicochemical data provided in the test plan.

### Category Definition

The category covers twelve sponsored substances each containing zinc salt complexes of O,O-bis alkyl or alkaryl esters of phosphorodithioic acid. The carbon number in these substances ranges from C12 to C72.

### Category Justification

The submitter's primary justification for the category is the structural similarity of the members and the presence of 10-15% highly refined lubricating base oil in the substances. The submitter expects the low water solubility and vapor pressure, in addition to the presence of the base oil, to play a major role in defining the physicochemical, environmental and ecotoxicological properties of these substances. The submitter also expects similarities in acute and chronic mammalian toxicities based on the structures and physicochemical properties of the substances.

There are 12 category members. For health effects, EPA suggests the category could usefully be divided into three subcategories: six mixed derivatives (C12 to C32) (Group 1), four having larger alkyl groups (C24-C40)(Group 2), and two alkylphenol derivatives with still larger alkyl groups (C72) (Group 3). However, there are no data available for the third group, and given their different structures, carbon content (C72), and significantly higher molecular weights, these chemicals may not be appropriate

members of the category with respect to extrapolation of health effects data to and from the other members.

## Test Plan

*Physicochemical data.* Log P data were provided for an analog (O-alkyl chain length < 8), but without experimental details. No additional testing was proposed by the submitter. Because of the large differences in carbon number range among the category members, EPA recommends that testing be performed on representative compounds, preferably the same substances proposed for aquatic toxicity testing.

*Environmental fate.* The submitter concludes that the zinc phosphorodithioic acid esters are resistant to hydrolysis because they lack a good leaving group. The submitter supports this statement by citing a study that examined the hydrolysis of zinc phosphorodithioic acid esters at high temperature (85°C) and very low pH. However, these compounds may have some susceptibility to hydrolysis under basic conditions and environmentally relevant conditions. Therefore, hydrolysis testing of representative substances from the alkyl (C12-C24) and alkaryl esters, including identification of hydrolysis products, appears warranted.

*Health effects.* The repeated-dose toxicity data (a total of 6 studies—3 on Group 1 and 3 on Group 2) include five 21-28 day dermal toxicity studies; none of them achieved a NOAEL (expressing the doses on a mg/kg/d basis would be helpful). The single oral study had a NOAEL of 10 mg/kg/day, based on mortality and neurotoxic effects. Effects in dermal and oral repeated-dose studies appear comparable (mortality, neurotoxic signs, effect on testes). There is only one reproductive/developmental toxicity study available (from Group 2) on a chemical that also has a 28-day oral toxicity study. EPA believes data from this pair of studies could be extrapolated to Group 1.

*Ecotoxicity.* The submitter's proposed testing in fish, invertebrates, and algae of a C18, a C32, and a C72 substance (these match the three groups suggested by EPA) appears acceptable. However, EPA suggests that a C24 category member be tested as well, owing to the broad carbon-number range among the proposed test substances. All substances should be tested at or below their water solubility limit; therefore, knowledge of the physicochemical properties is necessary to select the appropriate chemicals and achieve optimum test results. In some cases, depending on the physicochemical property information, chronic daphnia testing may be preferred over acute testing.

## Followup Activity

EPA requests that the submitter advise the Agency within 90 days of any modifications to its submission.